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Preparation, Standardization and Evaluation of Pharmaceutical Dosage Form

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ABSTRACT
Emulgel is a revolutionary medication delivery method that uses contemporary technologies to regulate the release of emulsion and gel. The stability of emulsion is increased, when it is incorporated into gel. The significant role played by alternative medicine in recent years led us to carry out a simple spectral study of some natural oils used in medical applications. The goal of the present study was to design and Characterisation of Emulgel of an Antifungal and Antibacterial activity of castor oil drug for vaginal infections. Gels showed acceptable results of properties like color, homogeneity, consistency, pH, viscosity, spreadability, extrudability and drug content etc. In all aspect the formulation F8 satisfied all the pharmaceutical parameter of emulgel and appears to be good topical agent.

Keywords: Castor oil, Emulgel, Intravaginal administration, Antifungal and Antibacterial agents.

I. INTRODUCTION

Currently, there is a huge interest in the scientific community and drug industry to exploit various mucosal routes of delivering drugs, which are poorly absorbed after oral administration. It is apparent that the human vagina remains to be a relatively unexplored route of drug delivery despite its potential as a non-invasive route of drug administration. The presence of dense network of blood vessels has made the vagina an excellent route of drug delivery for both systemic and local effect. The main advantages of vaginal drug delivery over conventional drug delivery are the ability to by-pass first pass metabolism, ease of administration and high permeability for low molecular weight drugs[1]

ANATOMY AND PHYSIOLOGY OF THE VAGINA

In the pharmaceutical literature, human vagina is often described as slightly S-shaped fibromuscular collapsible tubes between 6 and 10 cm long extending from cervix of the uterus. The vaginal wall consists of three layers: the epithelial layer, the muscular coat and the tunica adventia[2]

DRUG DELIVERY SYSTEMS FOR VAGINAL ADMINISTRATION

Vaginal delivery may be designed for administration of drugs by using an applicator or specifically designed systems for intravaginal administration. Further, vaginal formulations may be designed to produce local effect such as spermicidal or antibacterial effect or to produce a systemic effect by continuous release of drugs such as contraceptives[3]

FACTORS AFFECTING THE VAGINAL ABSORPTION OF DRUGS

Absorption of drug from vaginal delivery systems occurs in two main steps: drug dissolution in vaginal lumen and membrane penetration. Any biological or formulation factor that affects drug dissolution and membrane transport could potentially affect the absorption profile from vaginal drug delivery systems[1]

INRODUCTION OF EMULGEL[4,5,6]

As the name suggest the combination of gel and emulsion. Both oil-in-water and water-in oil type of emulsion used as vehicle to deliver various drugs to the skin. They also have a high capacity to penetrate the skin. The occurrence of gelling agent in water phase converts a standard emulsion into an emulgel. Emulgel for dermatological use have several advantageous properties such as non-staining, emollient, water soluble, easily removable, and translucent, good

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shelf life, spreadable and pleasing appearance.

FORMULATION CONSIDERATION[7]

The challenges in formulation of topical emulgel are:

1. Determining system that is non-toxic, non-irritating and non-sanitizing.
2. Formulating cosmetically elegant emulgel.
3.The emulgel formulation must have lower allergic potential, good physiological compatibility and high biocompatibility.

Emulgel is composed of two parts:

1. Emulsion
2. Gel

METHOD OF PREPARATION

Step1: formulation of emulsion either O/W or W/O
Step2: formulation of gel base
Step3: incorporation of emulsion into gel base with continuous stirring.

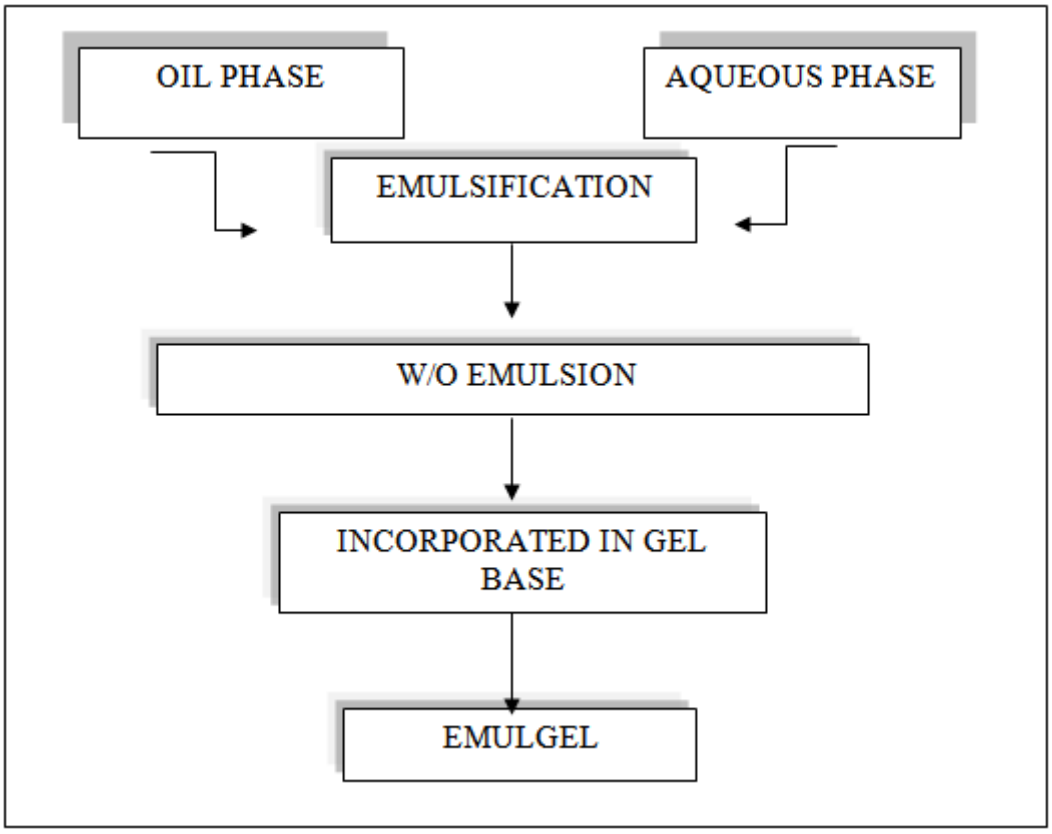

Table no.1: Method of Preparation

VAGINAL INFECTIONS

Over the last two decades, there has been a dramatic increase in the rate of superficial and invasive fungal infections. Approximately three-quarters of all women experience at least one episode of vulvovaginal candidiasis during their lifetime and nearly half of them suffer from multiple episode[8]

Vaginal infections with bacterial vaginosis, candidiasis and trichomoniasis are a global health problem for women[9] Abnormal vaginal discharge, itching, burning sensation, irritation and discomfort are frequent complaints among patients attending obstetrics and gynecology clinics[10]

Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge among women of reproductive age. The prevalence of BV is about 30 % in women of reproductive age.
Gonococcal infections are the second most common prevalent sexually transmitted bacterial infections

Chlamydia, Candida (yeast infection), Viral Vaginitis[11,12]

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HERBAL DRUG:

Castor is one of the oldest cultivated crops; however, it contributes to only 0.15% of the vegetable oil produced in the world. Castor beans are cultivated for their seeds yielding a viscous, pale yellow nonvolatile and nondrying castor oil. The unique structure of castor oil offers interesting properties, making it appropriate for various industrial applications. Castor oil is known to consist of up to 90% ricinoleic, 4% linoleic, 3% oleic, 1% stearic, and less than 1% linolenic fatty acids. Castor oil is valuable due to the high content of ricinoleic acid (RA), which is used in a variety of applications in the chemical industry[13]

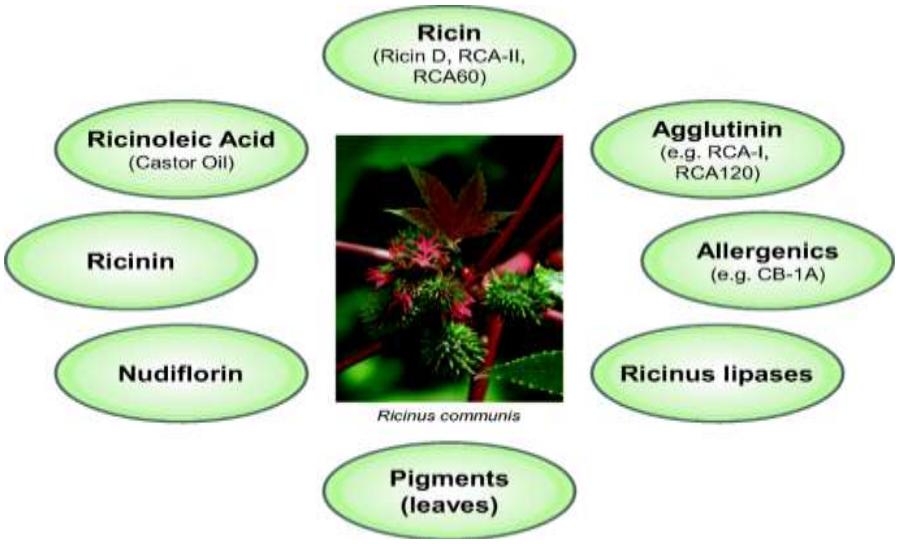

Fig. no. 1: Constituents of Ricinus communis

Mechanism Of Action: The main chemical that exerts castor oils laxative property is ricinoleic acid. In the intestine, lipase breaks down castor oil into ricinoleic acid, which activates EP3 and EP4 prostanoid receptors in smooth muscle cells. The activation of these receptors creates a transient calcium surge, which creates propulsion in the intestine. Due to this mechanism of action, castor oil falls in the stimulant laxative category, just like bisacodyl and sennosides. EP3 and EP4 prostanoid receptors are also present in the uterus, which leads to the possibility of castor oil's use for the induction of labor; however, more research is necessary on this subject.

Uses: Castor oil is mild purgative, fungistatic, used as an ointment base, as plasticizer, wetting agents, as a lubricating agent. Ricinoleic acid is used in contraceptive creams and jellies; it is also used as an emollient in the preparation of lipsticks, in tooth formulation, as an ingredient in hair oil. The dehydrated oil is used in the manufacture of linoleum and alkyl resin. The main use of castor oil is the industrial production of coatings, also employed to make pharmaceuticals and cosmetics in the textile and leather industries and for manufacturing plastics and fibres[14]

PREFORMULATION STUDY

Preformulation studies are first step in the rational development of dosage form of a drug. It can be defined as an investigation of physical and chemical properties of drug substance, alone and combined with Excipients. Purpose of preformulation testing is to produce information useful to the formulator in developing stable and bioavailable dosage forms, which can be produce at large scale.

1. **Authentication of drug**

A. UV Spectrum of Castor oil
B. FT-IR Spectroscopy
C. Solubility
D. Boiling Point
E. Refractive Index
F. Density

FORMULATION OF EMULGEL

Preparation of emulgel:

• All ingredients were weighed accurately according to the calculated quantities.
• Carbopol 934 soak in water (gel base).
• The water phase was stirred at a medium speed using overhead stirrer and gradually oil phase was added into it. Continued stirring it for about 15 min until emulsion was formed.

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• Add this emulsion in gel base and mix it properly.

• Adjust the pH addition of Triethanolamine.

FORMULATION TABLE:

Ingredients (%w/v)w/w)	F1	F2	F3	F4	F5	F6	F7	F8	F9
Castor oil	27	27	27	27	27	27	27	27	27
Carbopol934%	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5	1.5
Tween 80 %	3	4	5	3	4	5	3	6	4
Ethanol	4	5	5.5	4.5	5	5.5	5	7.5	6.5
Methyl Paraben	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Propyl Paraben	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15	0.15
Triethanolamine	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.	q.s.
Distilled water q.s.	Upto 100	Upto 100	Upto 100	Upto 100	Upto 100	Upto 100	Upto 100	Upto 100	Upto 100

Table no. 4: Formulation Table

EMULGEL EVALUATION

A. Physical Properties Of Formulation:[22]

1. Appearance[23]

Appearance of emulgel was evaluated on the bases of visual inspection.

2. Homogeneity[24]

The formulations were tested for their homogeneity by visual appearance after the emulgel was applied as thin layer on the slide.

3. pH measurement[24]

The pH measurements were done by using a digital type of pH meter by dipping the glass electrode into the emulgel.

4. Spreadability[22]

Spreadability refers to the extent of area to which gel readily spreads on application. It is determined by wooden block and glass slide apparatus. The time (Sec) taken by two slides to slip off from gel which is placed in between the slides under the direction of certain load is expressed as Spreadability. Smaller the time taken for the separation of two slides, better the Spreadability. Spreadability is calculated by using the formula: S = M.L / T Where, S = Spreadability M = Weight tide to the upper slide L = Length of a glass slide T = Time taken to separate the slide fully from each other.

5. Extrudability[25,26,27]

The emulgel were filled into collapsible tube after formulating them. The Extrudability of the formulation has been checked.

6. Rheological studies[23,27]

The viscosity of the different emulgel formulations is determined at 25°C using T-bar shaped spindle F96 (Helipath Stand Brookfield Viscometer-Brookfield engineering laboratories) and connected to a thermostatically controlled circulating water bath.

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B. CENTRIFUGATION

The centrifugation tests were performed at 25°C and at 2000 rpm for 5, 15, 30 and 60 min by placing a 10g of each formulation in a centrifuge tube having 1 cm diameter. Then the samples were evaluated regarding any phase separation and/or solid sedimentation

C. Differential Scanning Calorimetry (DSC):

Thermograms of castor oil and final optimized batch (F8) were obtained by using differential scanning calorimetry DSC 7020, Hitachi. Samples were weighed, a mass of 3 mg of Castor oil and final optimized bache (F8) in DSC aluminum crimped pans, and an empty pan were used as reference. DSC was performed at 30-300 °C temperature range at the rate of 10°C /min under N2 flow to provide an inert atmosphere during the measurement to prevent oxidation reaction.

D. DRUG CONTENT:[28]

Weigh accurately 1 gm of emulgel and it was dissolved in 100 ml of distilled water. The volumetric flask was kept for 2 hrs and shaken well in shaker to mix it properly to mix it properly. The solution was passed through the filter paper and filtered. The absorbance was measured spectrophotometrically after appropriate dilution against corresponding emulgel concentration as blank.

E. IN VITRO DIFFUSION STUDIES:

The in vitro drug release studies of the emulgel were carried out in Franz diffusion cell using the (cellophane membrane and mice skin). Emulgel (1gm) was spread uniformly on the rat skin. 11ml of the phosphate buffer of pH 7.4 was used as dissolution media which were added to the receptor compartment. This whole assembly was on magnetic stirrer and the solution on the receptor side was stirred continuously using a magnetic bead and temperature of the cell was maintained at 37±0.50C. Sample (1ml) was withdrawn at appropriate time intervals and replaced with the equal amounts of fresh dissolution media. Samples were analysed spectrophotometrically at 276 nm and the cumulative % drug release was calculated. The graph is plotted of % cumulative drug release versus time.

Diffusion protocol:

1. Diffusion apparatus: Franz diffusion cell
2. Temperature : 37±0.50C
3. RPM: 100
4. Diffusion medium (receptor compartment): PBS pH 7.4.
5. Volume of diffusion medium: 11ml
6. Volume of sample removed: 1ml
7. Sampling interval:1,2,3,4,5,6,7,8
8. Method of analysis: UV spectrophotometer at 276 nm for PBS pH 7.4.

F. DRUG RELEASE KINETICS

To investigate this in vitro drug release fate, numerous kinetic models have been used. The mathematical modelling of the data is divided as the mechanistic realistic models and the empirical and semi empirical models. A mechanistic, realistic mathematical model is built on equations that describe real phenomena, e.g. mass transport by diffusion, dissolution of drug and/or Excipients particles, and/or the transition of a polymer from the glassy to the rubbery state. These equations form the basis of mathematical theory. In the empirical models, mathematical treatment is purely descriptive and not based on ant physical, chemical and/or biological phenomena. Consequently, no or very limited insight into the underlying drug release mechanisms can be gained.

a. Zero-order model
b. First order model
c. Higuchi model
d. Hixson-Crowell model
e. Korsmeyer-Peppas equation

G. ANTIMICROBIAL STUDIES:

Determination of zone of inhibition method

In vitro antibacterial and antifungal activities were examined of the castor oil emulgel. Antibacterial and Antifungal activities of emulgel was performed against two pathogenic bacteria and two pathogenic fungi were investigated by the agar cup method.

For the determination of zone of inhibition, pure Gram-positive, Gram-negative, and fungal strains were taken by as a standard antibiotic for comparison of the result. Castor oil emulgel was screened for their antibacterial and antifungal activities against the Escherichia coli, Staphylococcus aureus and fungi Candida albicans, Aspergillus niger. The sets of three dilution (100, 150, and 200 µg/ml)of Castor oil emulgel and standard drug were prepared in double-distilled water using nutrient agar tubes. Agar plates were

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taken and allowed to stay at 37°C for 3 hrs. Control experiments were carried out under similar condition by using Clindamycin solution for antibacterial activity and Clotrimazole solution for antifungal activity as Standard drugs. The zones of growth inhibition around the disk were measured after 18 to 24 hrs of in incubation at 37°C for bacteria and 48 to 98hrs for fungi at 28°C.The sensitivities of the microorganism species to the emulgel were determined by measuring the sizes of inhibitory zones (including the diameter of disk)on the agar surface around the disk.

H. MOTIC DIGITAL MICROSCOPE:

Prepared Antifungal Emulgel can be placed on glassslide at room temperature and then the surface morphology of the Emulgel can be studied by Motic Digital Microscopy. The morphology of Castor oil Antifungal Emulgel was examined with a Motic Digital Microscopy. The sample was mounted on a glass slide and observed under 10X object.

I. STABILITY STUDIES:

The purpose of stability testing is to define the shelf life of formulated pharmaceutical be used by the patient. However, prior knowledge of the drug's stability is needed early in the development process in order to assist with formulating it. Therefore, different approaches to the evaluation of stability are needed at the different stages of product development.

Also stability testing provide an evidence on how the quality of drug product varies with time under the influence of a variety of environmental factors, such as temperature, humidity and light and to establish a retest period for the drug substance or shelf life for the drug product and recommended storage conditions.

Experimental method for stability studies:

The optimized formulation was prepared packed in aluminium collapsible tubes and subjected to stability studies at 40˚C / 75% RH for a period of 3 months. Samples were withdrawn at 1 month time interval and evaluated for physical appearance, pH, rheological properties, drug content and drug release.

II. RESULT AND DISCUSSION:

Result and discussion for Preformulation studies:

1. AUTHENTICATION OF DRUG:

A. UV Spectrum of Castor Oil-

The solution of Castor oil in ethanol was found to exhibit maximum absorption (λmax) at 340nm after scanning in the range of 200-400nm.

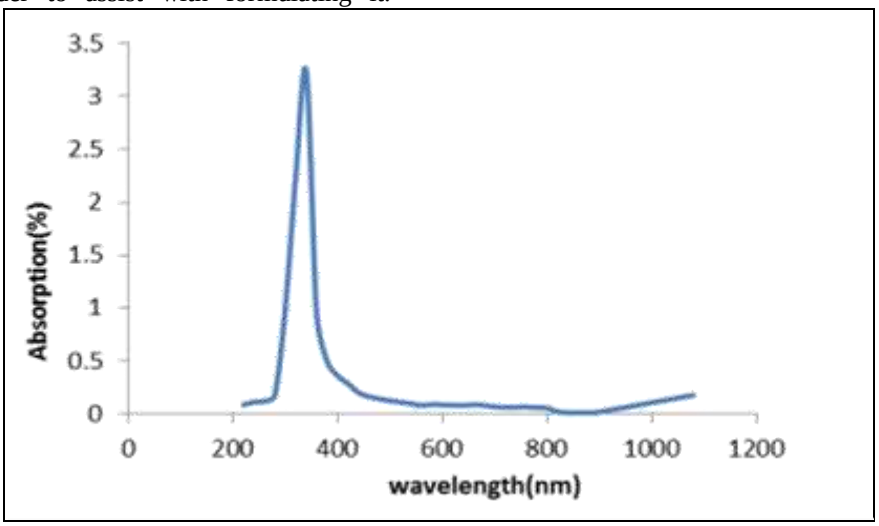

Fig. no. 2: UV Spectrum of Castor oil

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Construction of Calibration Curve: UV method:

Calibration Curve of Castor oil- Drug

CONCENTRATION (µg/ml)	ABSORBANCE
2	0.112
4	0.215
6	0.321
8	0.412
10	0.489
12	0.521
14	0.745
16	0.816
18	0.911
20	0.968
22	1.121

Table no. 5 : Calibration of Castor oil in Ethanol

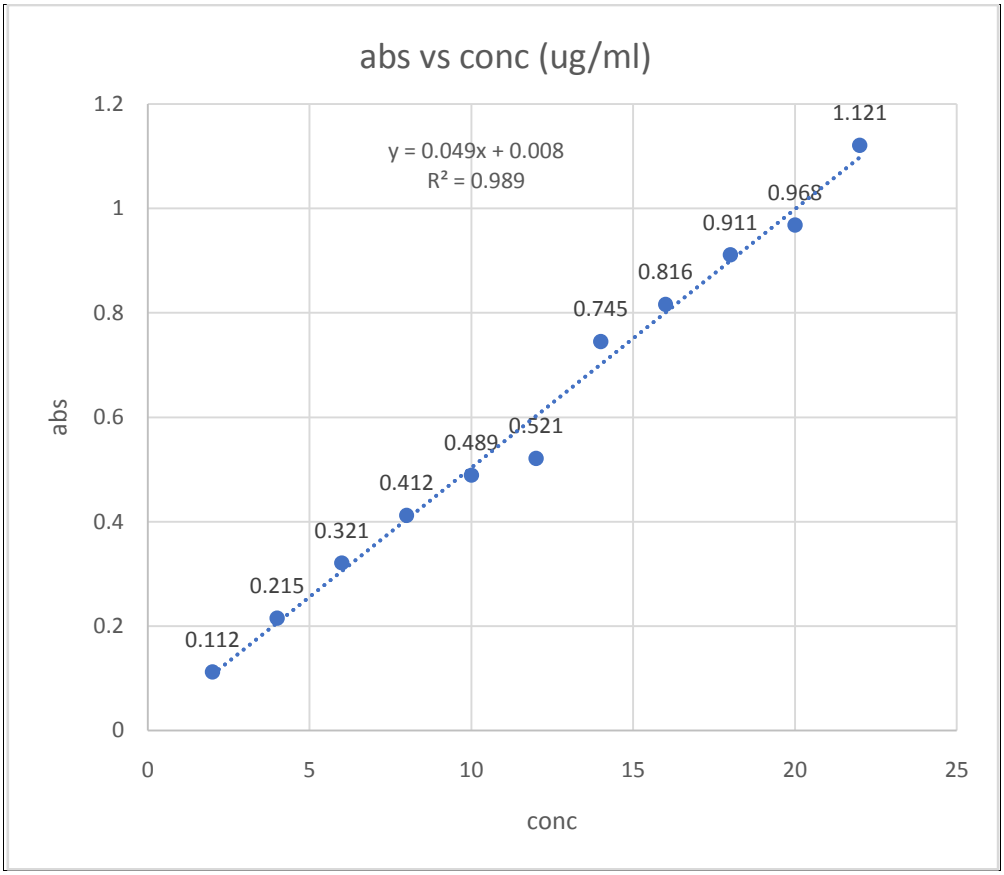

Figure no. 3 : Calibration Curve of Castor oil in Ethanol

B. Fourier Transformation Infrared (FTIR) Spectroscopy :

The identity of drug was confirmed by comparing IR spectrum.

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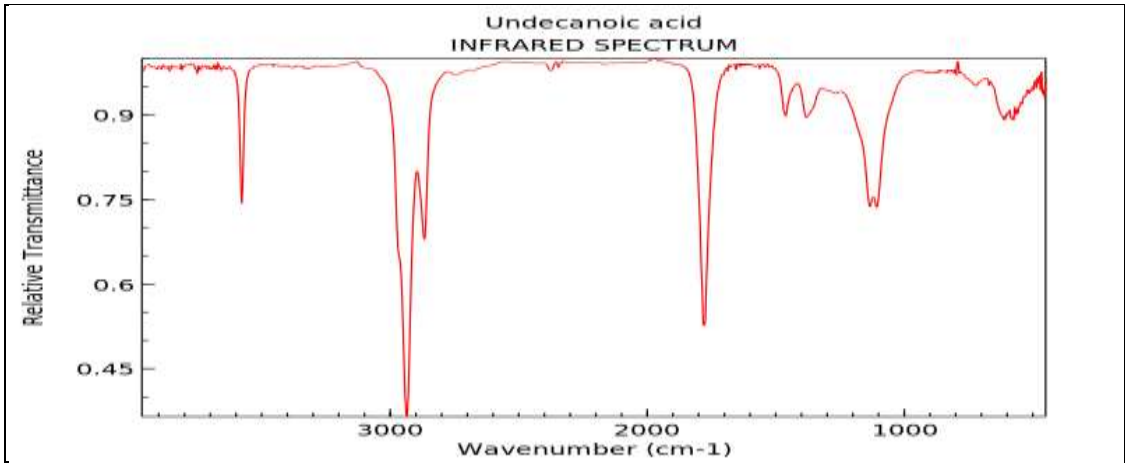

Figure no. 4 : FTIR of Pure Castor oil Drug

FTIR values of Castor oil:

Peak Range (cm-1)	Bond and Functional group
2800	(C-H) Alkane
3700	(O-H) Alcohol
1750	(R-COO-R), (-C=C) Ester, Aromatics
1100	(C-O) Ether

Table no. 6 : IR values of Castor oil

Result : It can be concluded that the API that is being used in the pre-formulation studies and ultimately in the formulation is pure.

C. Boiling point:

Boiling point of Castor oil was found to be 313 °C.

2. DRUG EXCIPIENTS COMPATIBILITY STUDIES USING (FT-IR) SPECTROSCOPY :

The FTIR spectra of the pure drug and drug-Excipients physical mixture indicate that characteristics bands of the drug were not altered, without any change in their position, indicating no chemical interaction between the drug and Excipients used.

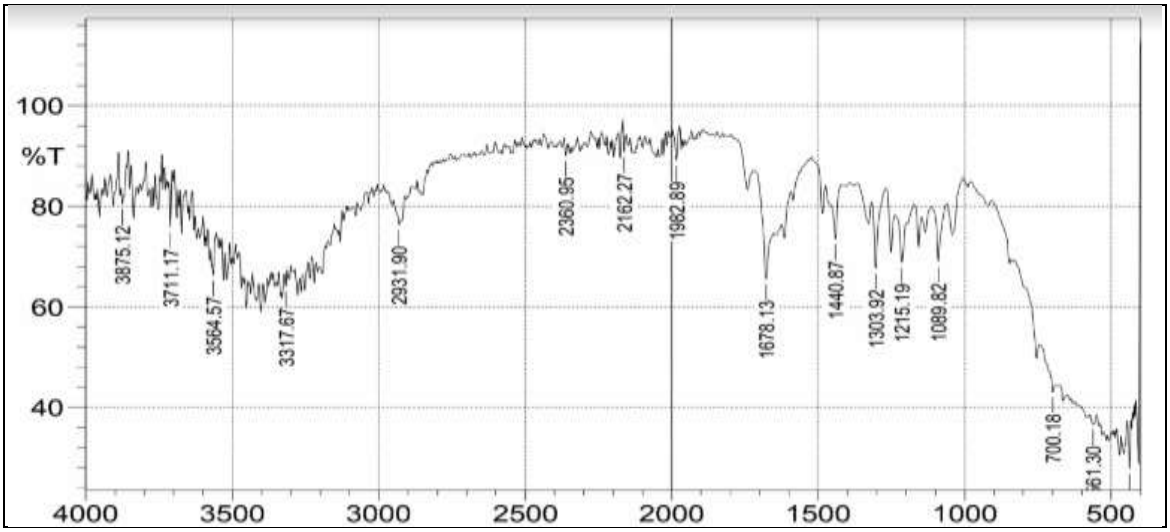

Figure no. 5: FT-IR of emulgel formulation

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3. SELECTION OF OIL PHASE:

1. Castor oil has a high content of unsaturated omega 9-fatty acid and hydroxyl acid (stearic, oleic and linoleic acid.Itcontains the biochemical agent undecylenic acid, which is used to stop fungal growth.
2. Several studies indicated that fatty acids reduce the levels of fungal infections.
3. Based on investigation, undecyclenic acid (undecanoic acid) is one of the active compounds in castor oil and justify the anti-fungal properties.

• **Selection of emulsifier:** Tween 80

• **Selection of gel phase:**

Carbopol-934 form gel at very low concentration and provide controlled release of incorporated drug whereas carbopol-940 form highly viscous gels and provide controlled release of incorporated drug. Thus, Carbopol 934 was selected.

4. RESULT AND DISCUSSION FOR EVALUATION OF EMULGEL FORMULATION:

1. PHYSICAL PROPERTIES OF FORMULATION

Batches	Appearance	Phase Separation	pH	Viscosity	Homogeneity	Spreadability	Extrudability
F1	White viscous creamy	none	4.38	127.56	+++	14.36	++
F2	White viscous creamy	none	4.46	166.56	++	12.35	++
F3	White viscous creamy	none	4.49	126.35	+++	15.06	++
F4	White viscous creamy	none	4.58	152.44	+++	14.25	++
F5	White viscous creamy	none	4.69	126.04	++	13.62	++
F6	White viscous creamy	none	4.82	178.53	+++	16.03	++
F7	White viscous creamy	none	4.32	119.42	++	13.25	+
F8	White viscous creamy	none	4.05	142.23	++	15.69	+++
F9	White viscous creamy	none	4.28	199.40	+++	16.36	++

Mean ±SD, n=3 + Average, ++ Good, +++ Excellent

Table no. 7: Physical properties

2. DRUG CONTENT:

Batches	F1	F2	F3	F4	F5	F6	F7	F8	F9
Drug content	56.2	43.51	78.29	60.52	69.12	87.26	67.56	95.13	84.23

Table no. 8: Drug content

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3. IN VITRO DIFFUSION STUDIES

Time(hr.)	F1	F2	F3	F4	F5	F6	F7	F8	F9
1	8.84	9.27	11.56	8.13	9.23	12.98	8.09	9.36	10.79
2	13.21	17.29	23.93	13.95	16.21	22.49	15.08	23.15	32.69
3	17.38	23.74	31.32	17.25	20.5	31.83	22.42	31.78	43.98
4	22.25	32.88	43.03	21.26	24.49	43.01	32.85	39.56	54.17
5	30.01	41.22	57.23	28.04	31.22	57.17	47.01	57.34	60.29
6	39.78	48.12	61.49	33.28	40.08	69.3	51.23	65.26	69.5
7	43.02	56.02	63.13	42.17	54.72	73.12	54.59	82.75	77.02
8	47.08	60.15	70.2	48.03	65.53	79.67	57.01	90.14	88.65

Table no. 9: In vitro drug release of F1-F9 and marketed formulation shows percent cumulative drug release

4. RELEASE KINETICS OF OPTIMIZED BATCH:

Time (min)	% Drug Release
0	0
30	15
60	27
90	40
120	50
150	57
180	69
210	76

Table no. 10: Release kinetics of optimized batch F8

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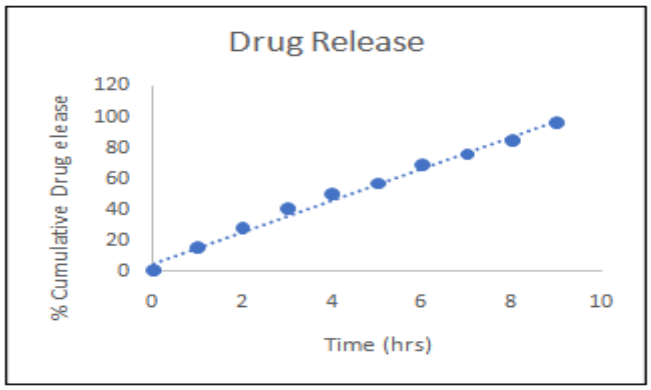

Figure no. 6 : Drug Release of Optimized Batch

Release Kinetic Studies:

The optimized batch (F8) was subjected to release kinetic studies and results are as follows;

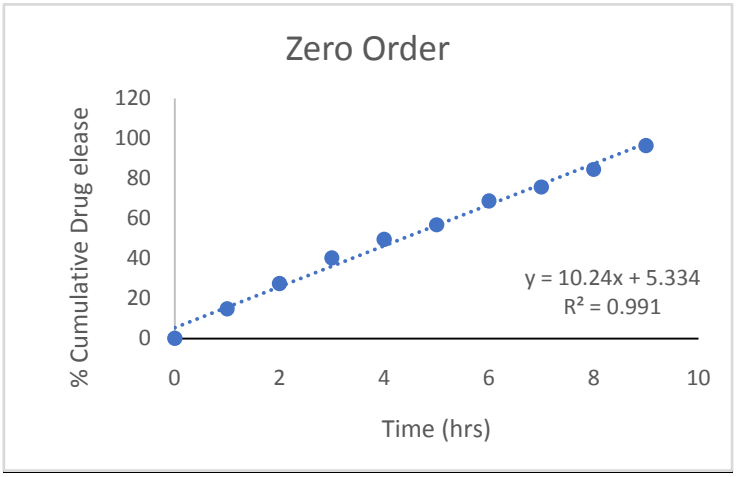

Figure no. 7: Zero Order Plot

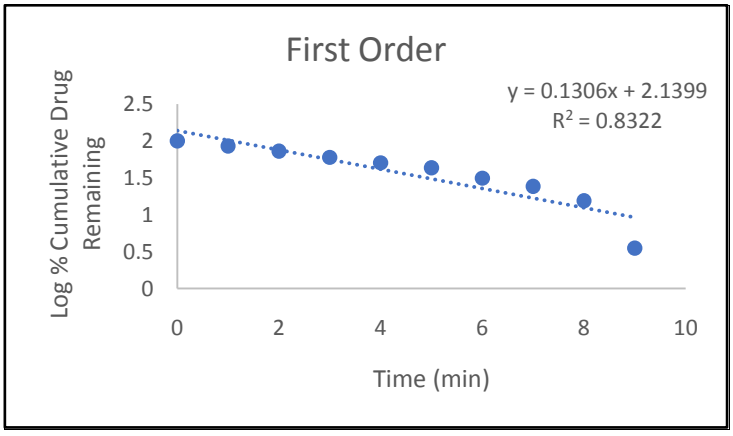

Figure no. 8 : First Order Plot

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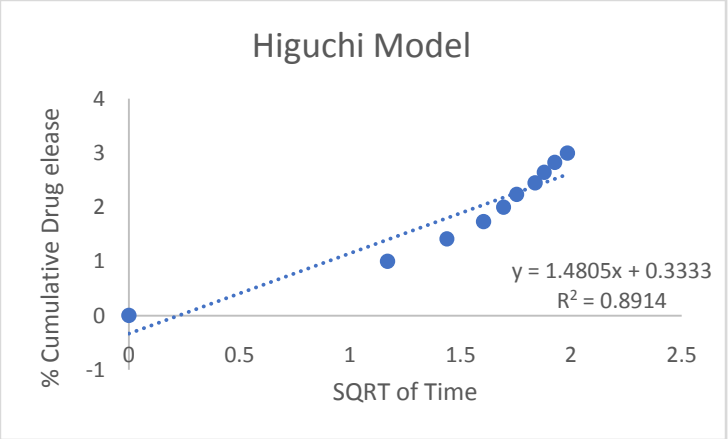

Figure no. 9: Higuchi Model

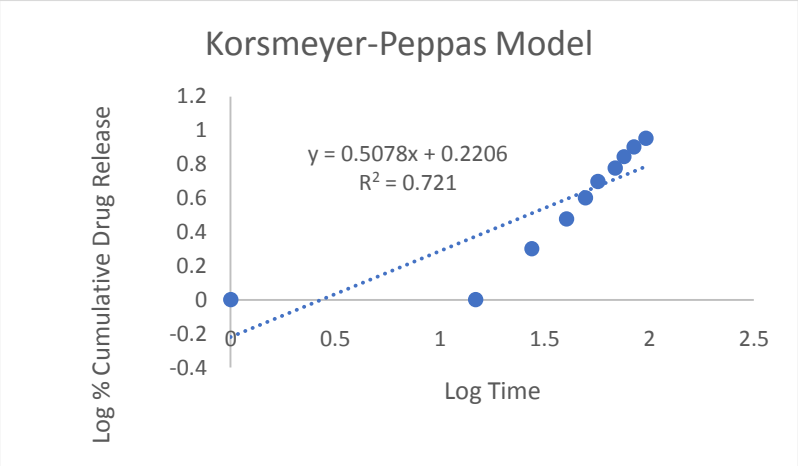

Figure no. 10: Korsmeyer-Peppas Model

Release kinetic model	Regression coefficient
Zero order	0.9837
First order	0.8645
Higuchi model	0.8786
Hixscon-crowell model	0.9232
Krosmeyer-Peppas model	0.6911

Table no. 11: Kinetic Studies R2 Values

5. DIFFERENTIAL SCANNING CALORIMETRY (DSC) :

The DSC of the Castor oil showed endothermic reaction at 36.8°C.

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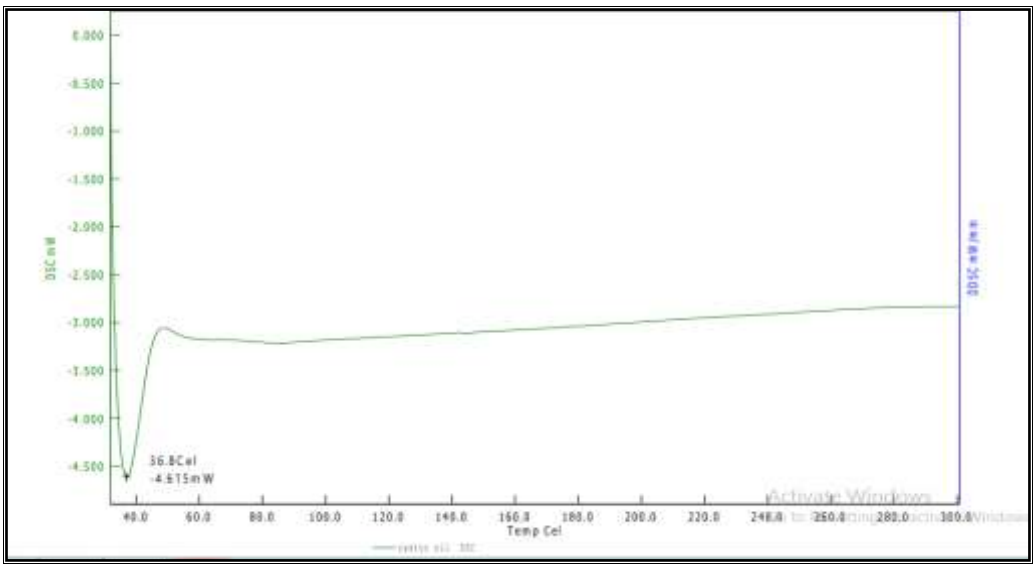

Figure no. 11: DSC of Castor oil -Drug

The DSC of the Optimized Batch (F8) showed endothermic reaction at 103.4 °C.

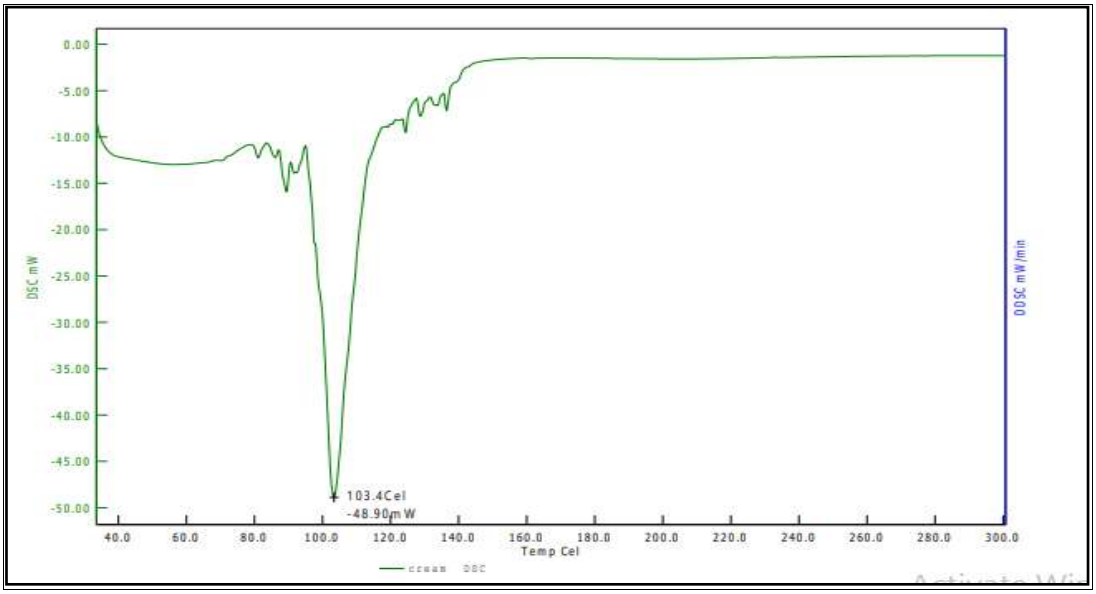

Figure no. 12: DSC of Optimized Batch (F8)

Result: It can be concluded that the API and Excipients that is being used in the preformulation studies and ultimately in the formulation is pure.

6. ANTIMICROBIAL STUDIES:

The antimicrobial activity of the castor oil emulgel was studied in different concentrations (100, 150, and 200µg/ml). Antibacterial and Antifungal potential of emulgel were assessed in terms of zone of inhibition of bacterial growth.

The results show that the emulgel was found to be more effective against all the microbes tested.

ANTIFUNGAL ACTIVITY (Zone of inhibition in mm)				
Test Sample	**Microorganism**	**Concentration in µg/ml**		
		100 µg/ml	**150 µg/ml**	**200 µg/ml**
Aqueous extract of Drug	**Candida albican**	**24**	**25**	**26**

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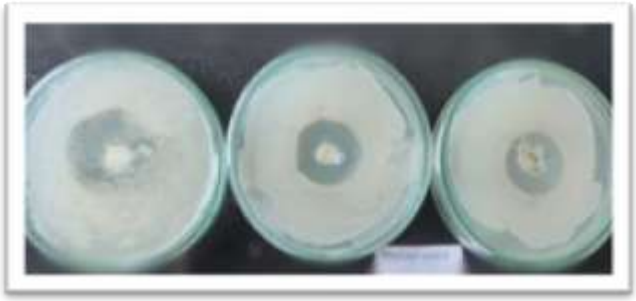
Marketed Drug (Clotrimazole solution)		**23**	**23.6**	**24**
Aqueous extract of Drug	**Aspergillus niger**	**26**	**27**	**29**
Marketed Drug (Clotrimazole solution)		**25**	**26**	**27**

Table no. 12: Antifungal activities of Aqueous extract of Castor oil and Marketed Product

ANTIFUNGAL ACTIVITY ON AGAR PLATES

C. Albican on Aqueous extract of drug



C. Albican on Clotrimazole solution

A. Niger on Aqueous extract of drug

A. Niger on Clotrimazole solution

Figure No. 13: Agar Plate test for antifungal activity

ANTIBACTERIAL ACTIVITY (Zone of inhibition in mm)				
Test Sample	**Microorganism**	**Concentration in µg/ml**		
		100 µg/ml	**150 µg/ml**	**200 µg/ml**
Aqueous extract of Drug	**Escherichia coli**	**28**	**29**	**29.6**
Marketed Drug (Clindamycin solution)		**27**	**28**	**28.3**
Aqueous extract of Drug	**Staphylococcus aureus**	**26**	**28**	**30**

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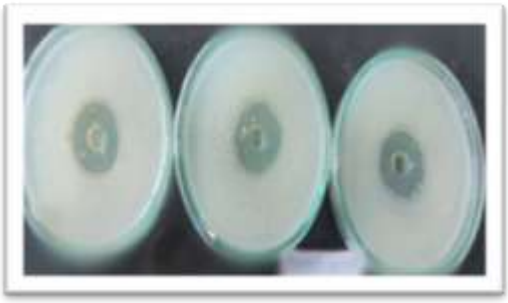
Marketed Drug (Clindamycin solution)		**22**	**27**	**29**

Table no. 13: Antibacterial activities of Aqueous extract of Castor oil and Marketed Product

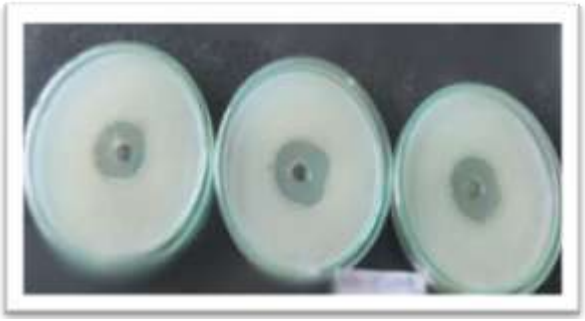
ANTIBACTERIAL ACTIVITY ON AGAR PLATES

E. Coli on Aqueous extract of drug

E. Coli on Clindamycin solution



S. Aureus Aqueous extract of drug

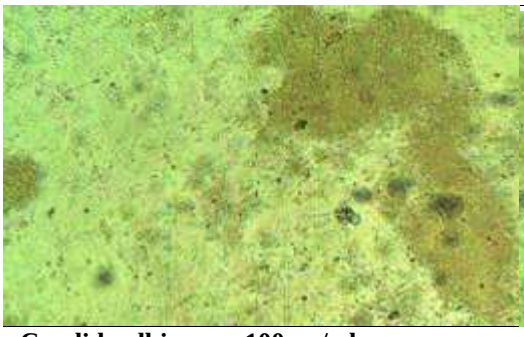


S. Aureus on Clindamycin solution

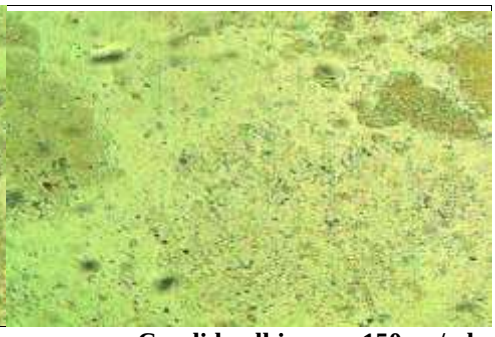
Figure No. 13: Agar Plate test for antibacterial activity

7. MOTIC DIGITAL MICROSCOPE:

Image of Antifungal emulgel Optimized formulation of Emulgel by Motic Digital microscope. Images are taken from the area of zone of inhibition.



Candida albicans – 100 µg/ml



Candida albicans – 150 µg/ml

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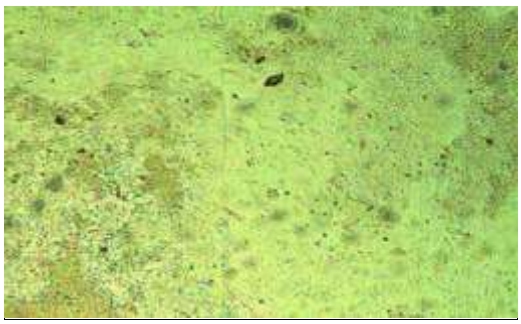
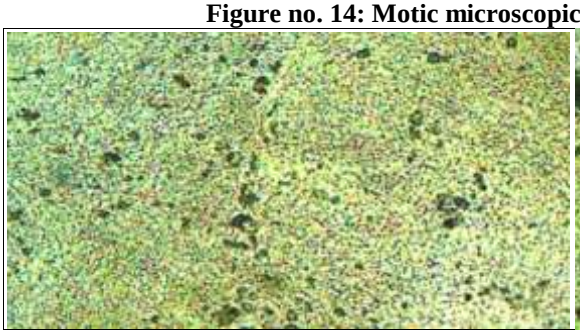
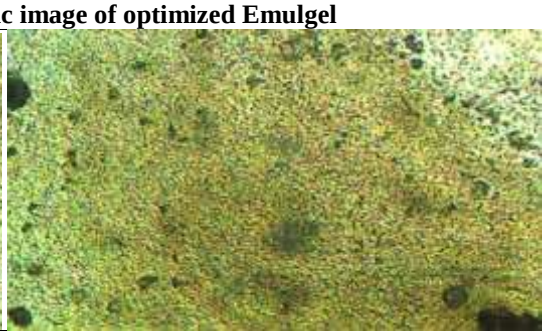


Candida albicans – 200 µg/ml

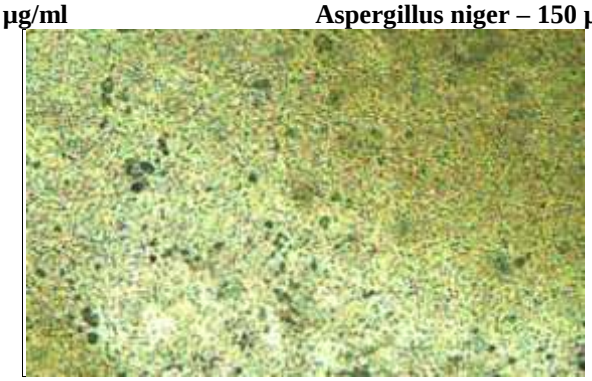
Figure no. 14: Motic microscopic image of optimized Emulgel



Aspergillus niger – 100 µg/ml

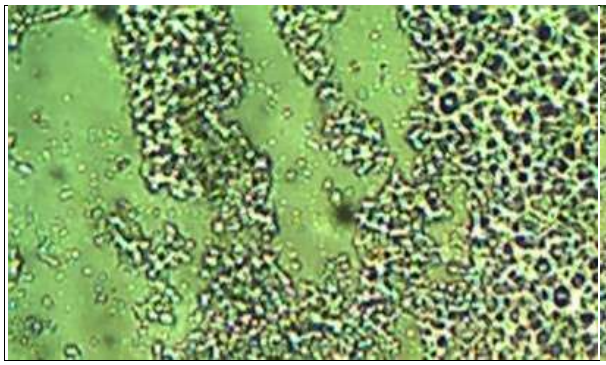


Aspergillus niger – 150 µg/ml

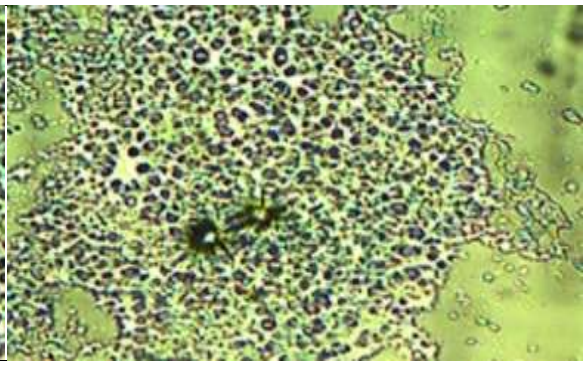


Aspergillus niger – 200 µg/ml

Figure no. 15: Motic microscopic image of optimized Emulgel



Escherichia coli – 100 µg/ml



Escherichia coli – 150 µg/ml

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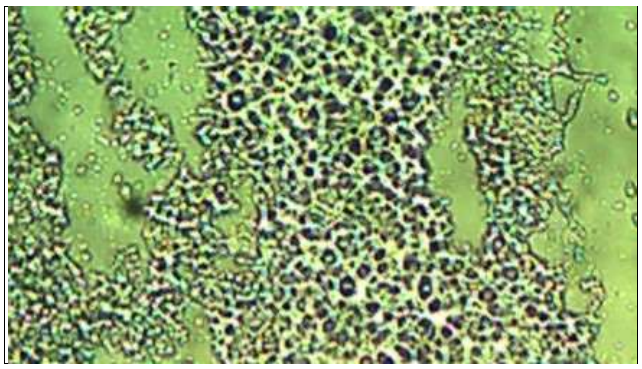
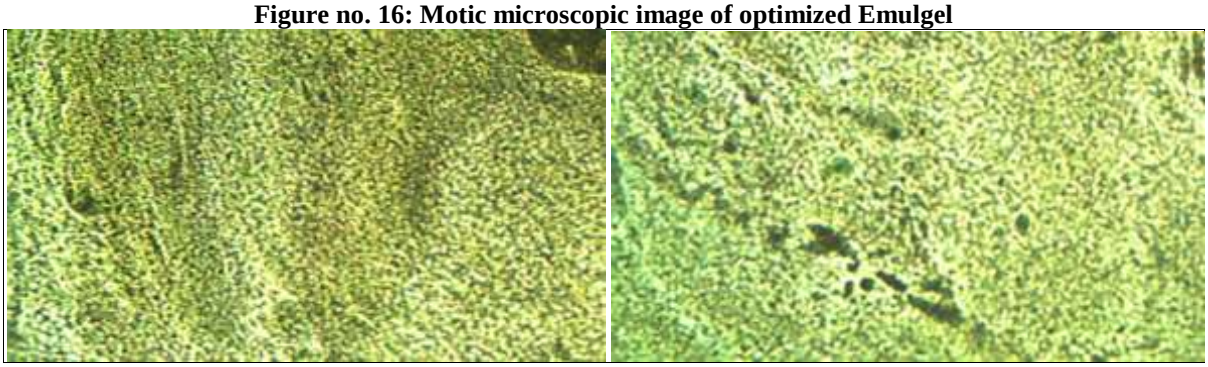
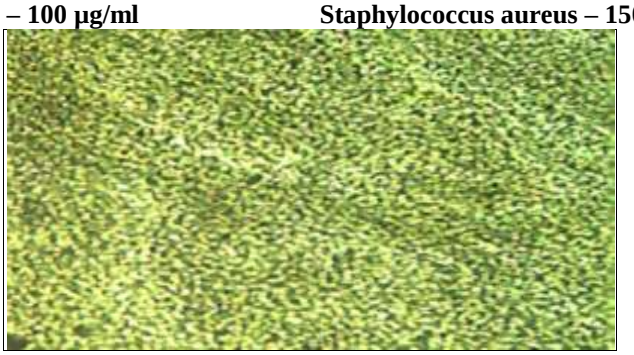


Escherichia coli – 200 µg/ml

Figure no. 16: Motic microscopic image of optimized Emulgel



Staphylococcus aureus – 100 µg/ml **Staphylococcus aureus – 150 µg/ml**



Staphylococcus aureus – 200 µg/ml

Figure no. 17: Motic microscopic image of optimized Emulgel

8. STABILITY STUDIES:

Optimized formulation was packed in aluminium collapsible tubes and subjected to stability studies at 40±20C/75±5% RH for duration of two months.

Evaluation parameters	1 month	2 month	3 month
Appearance	White viscous creamy	White viscous creamy	White viscous creamy
Phase separation	None	None	None
pH	4.89	4.51	4.63
Viscosity	16238.47	16238.47	16238.47

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Homoeneity	+++	+++	++
Spreadability	16.36	16.58	16.50
Excrudability	+++	+++	++
In vitro drug realease	90.14	87.15	87.02
Drug content	95.13	95.02	94.72

Table no. 14: Result of Stability study

III. CONCLUSION:

IR spectra shown that there was no chemical interaction between drug and polymer.

All the batches were studied for physicochemical parameters such as Spreadability, homogeneity, Extrudability, pH, viscosity and consistency and found satisfactory.

Three-month stability study of optimized batch F8 indicates no change in physical and chemical parameters. Compatibility studies showed no significant interactions between drug andexcipients. In conclusion, it is suggested that the prepared formulation is a better option forinfection caused by Bacteria and Fungi. The optimized batch followed Zero order model release kinetics. This study can be extended in human patients.

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